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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,884	08/10/2001	Gary Van Nest	377882001720	5141

25226 7590 05/01/2003

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EXAMINER
GIBBS, TERRA C

ART UNIT	PAPER NUMBER
1635	10

DATE MAILED: 05/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

3M.

Office Action Summary	Application No.	Applicant(s)	
	09/927,884	VAN NEST ET AL.	
	Examiner	Art Unit	
	Terra C. Gibbs	1635	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-79 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-79 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-79 are pending in the instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15, 18, 19, 20-25, 28, 29, 56-70, 73, 74, 75, 76, and 77, drawn to an immunomodulatory polynucleotide/microcarrier (IMP/MC) complex comprising a polynucleotide comprising an immunostimulatory sequence (ISS) linked to a biodegradable microcarrier (MC), with the proviso that if the MC is gold, latex or magnetic, the linkage is other than by biotin/avidin and a kit comprising said immunomodulatory polynucleotide/microcarrier (IMP/MC) complex, classifiable in class 536, subclass 24.3.

II. Claims 1, 9, 12, 13, 14, 15, 16, 17, 20, 26, 27, 71, 72, 76, 78 and 79, drawn to an immunomodulatory polynucleotide/microcarrier (IMP/MC) complex comprising a polynucleotide comprising an immunostimulatory sequence (ISS) linked to a biodegradable microcarrier (MC), with the proviso that if the MC is gold, latex or magnetic, the linkage is other than by biotin/avidin and a kit comprising said immunomodulatory polynucleotide/microcarrier (IMP/MC) complex, wherein said complex further comprises an antigen, classifiable in class 536, subclass 24.1.

III. Claims 30-51, 54 and 55, drawn to a method of modulating an immune response in an individual comprising administering to an individual a composition comprising an immunomodulatory polynucleotide/microcarrier (IMP/MC) complex comprising a polynucleotide linked to a biodegradable microcarrier (MC), classifiable in class 435, subclass 4.

IV. Claims 30, 44, 47, 48, 49, 50, 52 and 53, drawn to a method of modulating an immune response in an individual comprising administering to an individual a composition comprising an immunomodulatory polynucleotide/microcarrier (IMP/MC) complex comprising a polynucleotide linked to a biodegradable microcarrier (MC), wherein said composition further comprises an antigen, classifiable in class 435, subclass 7.22.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I and II are unrelated, each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions of Groups I and II are unrelated and distinct because they employ different molecules with different chemical and physical structures so that independent searches of the prior art would be required that would constitute a serious burden on the Examiner. For example, a search of the immunomodulatory polynucleotide/microcarrier

(IMP/MC) complex of Group I would not encompass all of the art relevant to the immunomodulatory polynucleotide/microcarrier (IMP/MC) complex, wherein said complex further comprises an antigen of Group II. They are materially distinct compositions which differ in antigen complexity. The differences between Inventions I and II are further underscored by their different classifications and independent search status. Thus, they are unrelated and patentably distinct from each other.

Although the methods of Groups III and IV are related because they encompass a method of modulating an immune response in an individual comprising administering to an individual a composition comprising an immunomodulatory polynucleotide/microcarrier (IMP/MC) complex comprising a polynucleotide linked to a biodegradable microcarrier (MC), they are patentably distinct from each other. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to related methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: They employ different molecules with different chemical and physical structures so that independent searches of the prior art would be required that would constitute a serious burden on the Examiner. For example, a search of the immunomodulatory polynucleotide/microcarrier (IMP/MC) complex of Group III would not encompass all of the art relevant to the immunomodulatory polynucleotide/microcarrier (IMP/MC) complex, wherein said complex further comprises an antigen of Group IV. They are materially distinct methods which differ in reagents and/or dosages and/or schedules used, response variables, criteria for success, and antigen complexity. The differences between Inventions III and IV are further

underscored by their different classifications and independent search status. Thus, they are unrelated and patentably distinct from each other.

Inventions of Groups I and II are related to the method inventions of Groups III and IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products can be used in materially different processes of use. For example, the immunomodulatory polynucleotide/microcarrier (IMP/MC) complex of Groups I and II can be used as a hybridization probe, which is a materially different process than a method of modulating an immune response in an individual comprising administering to an individual a composition comprising an immunomodulatory polynucleotide as in Groups III and IV.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is (703) 306-3221. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

tcg
April 25, 2003

RAM SHUKLA
PRIMARY EXAMINER